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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,220	07/29/2003	Anton F. J. Fliri	PC10886B	5332
23913	7590	07/22/2005	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,220

Applicant(s)

FLIRI ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 12-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,12-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of the petition to revive instant application on 5/4/05, the amendment filed 3/29/05 has been entered and the following still applies .

While applicants have amended part of the claims to remove nonelected subject matter much more remains. In claim 1, "A" is still present which encompasses bridged ring systems of various sizes. The variable should be deleted or indicated as absent along with the bonds emanating from it. Also, R1/R2 forming rings together is still present as are one of R1/R2 forming rings with R7 as are R3/R4 forming rings with R7. See pages 4-6 of claim 1 as well as claim 13.

Claims 15-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Reason #1 of the previous action remains. Applicants urge dosages **may** be different for the composition claims but all these claims recite the same uses so its not clear how changing the wording modifying "amount" materially changes the dosage and there is nothing in the specification directing one to a different set of dosage ranges for one use vs. another. At any rate the intended uses in composition claims are given no material weight. Art teaching a different pharmaceutical use would still anticipate these claims. It is not evident from a

reading of the specification that any one composition is specially adapted for one use vs another. Thus it remains unclear how one can infringe one of the these claims without infringing the other two. While the preamble in claims 20 and 22 are given material weight it is noted they are identical and again the effective amounts are not seen to materially differ based on specification .

2. Reason #2 of the previous action also remains. While diseases are mentioned in the specification none are recited in the method claims and thus intended scope is not readily ascertainable for the reasons given in the previous action.

Claims 1,3,4 and 12-32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Both rejections of the previous action are maintained notwithstanding applicants' traverse. With regard to the scope of compounds claimed, while it is agreed that not every member need be tested, simply asserting that the entire genus has D3 activity does not automatically avoid an enablement rejection. If it did, the factors discussed in In re Wands and the MPEP would not have to be evaluated. Given the many factors that do pertain in the instant case as discussed in previous actions there is reason to

question efficacy of the instant scope given the **homogeneity** of the prepared examples. The comment made by applicants that the acylamino cyclopropane structure is responsible for activity is not persuasive. The test data presented on p.25 of the specification clearly shows that the nature of substituents on the piperazine backbone affect activity and in the absence of any examples containing representative heterocyclic substituents at the many R variables permitted there is no assurance that variation of such is not structure-sensitive to D3 binding. A similar argument was made in *In re Cauvallito* (127 USPQ 202)- see especially right column at p.205 and left column, p.206.

A recent Board decision, namely, *Ex parte Varshavsky* in 63 USPQ2d 1486, decided that a high level of skill in the art was not sufficient to override other Wands factors that demonstrated undue experimentation for the **full** scope claimed.

With regard to the scope of uses still covered by the method claims, while applicants state that the D3 receptor has been cloned in 1990, it is not seen how this fact equates with reasonable expectation of treatment for the many uses still claimed. Applicants have not addressed much less refuted the references previously cited by the examiner.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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A handwritten signature in cursive script, appearing to read "E Bernhardt".

Emily Bernhardt
Primary Examiner
Art Unit 1624